Clinical and Translational Science Awards

1st Principal Investigators Meeting

Building 31, 6th Floor, Conference Room 6
31 Center Drive, Bethesda, MD 20892

October 23, 2006

Participants

Principal Investigators/Awardees

Frank Arnett, M.D., University of Texas Health Sciences Center, Houston
Lars Berglund, M.D., Ph.D., University of California, Davis
Robert Califf, M.D., Duke University
Barry Coller, M.D., Rockefeller University
Garret Fitzgerald, M.D., University of Pennsylvania
Henry Ginsberg, M.D., Columbia University
David Guzick, M.D., Ph.D., University of Rochester
Mike McCune, M.D., Ph.D., University of California, San Francisco
Eric Orwoll, M.D., Oregon Health and Science University
Stephen Reis, M.D., University of Pittsburgh
Robert Rizza, M.D., Mayo Clinic College of Medicine
Robert Sherwin, M.D., Yale University

NIH

Duane Alexander, M.D., National Institute of Child Health and Human Development
Barbara Alving, M.D., National Center for Research Resources
Elaine Collier, M.D., National Center for Research Resources
John Gallin, M.D., NIH Clinical Center
Anthony Hayward, M.D., Ph.D., National Center for Research Resources
Stephen Katz, M.D., Ph.D., National Institute of Arthritis and Musculoskeletal Diseases
Michael Kurilla, M.D., National Institute of Allergy and Infectious Disease
John Marler, M.D., National Institute of Neurological Disorders and Stroke
Lori Mulligan, MPH, National Center for Research Resources
Iris Obrams, M.D., Ph.D., National Center for Research Resources
Gail Pearson, M.D., National Heart, Lung, and Blood Institute
Bruce Pihlstrom, D.D.S., National Institute of Dental and Craniofacial Research
Susan Shurin, M.D., National Heart, Lung, and Blood Institute
Betty Tai, Ph.D., National Institute on Drug Abuse

Meeting Summary

Welcome and Introductions

Barbara Alving, M.D., of the National Center for Research Resources (NCRR), Anthony Hayward, M.D., Ph.D. (NCRR), and Michael Kurilla, M.D., of the National Institute of Allergy and Infectious Diseases (NIAID) opened the meeting at 9:00 AM. Principal Investigators, NIH participants and videoconference-connected key personnel introduced themselves.

Introduction of the CTSA Program

After Dr. Hayward provided an overview of the Clinical and Translational Science Award (CTSA) Program, the PIs and the NIH Clinical Center Director gave the following assessments of their needs:

Califf (Duke University) cited a need to move clinical research beyond a single institution, emphasizing the importance of public-private partnerships and developing data standards and clinical nomenclature for bioinformatics purposes.

Coller (Rockefeller University) listed 5 goals: (1) establish national research nursing standards and certification; (2) share research pharmacy best practices; (3) develop more computationally minded translational scientists; (4) establish a national phenotype program with formal ontologies; and (5) develop a national clinical research outcome assessment tool. He described a Pilot Participant Survey that they would like to validate in the CTSA consortium.

Fitzgerald (Pennsylvania) would: (1) break down intra and inter-institutional barriers (e.g., between pediatric and adult medicine) and, (2) develop investigators who can cross the translational divide.

Berglund (UC Davis) would share collective experiences and tests broadly with clinical researchers both among and outside of CTSAs to develop common benchmarks for progress.

Orwoll (Oregon) will pursue inter-institutional benefits in informatics, education, pediatric and community-based research, working also for intra-institutional advances in organizational strategies. He urged that the organization of cores, academic-industry consortia and intellectual property issues be addressed.

Rizza (Mayo) wants to speed IRB processes and develop bioinformatics cores to keep track of massive amounts of data. Need to maintain basic GCRC functions such as research nursing and use the CTSA as a tool to shape academic health center plans.

McCune (UCSF) stressed improved training, so trainees can better navigate the infrastructure and have more confidence in a research career: a virtual community could help.

Reis (Pittsburgh) has patient and community education about clinical research as a priority, along with virtual collaborations, pilot programs, creative solutions to regulatory issues; academic-industry collaborations; and collaborations on specific high-impact research studies. We need to consider each CTSA site as an alpha test site to develop and pilot innovative programs. The National Consortium can be considered to be a beta test site to evaluate the effectiveness of programs that are developed at individual CTSA sites prior to dissemination to the nation (translation to health practice).

Sherwin (Yale) recommended a "jump start" meeting in which PIs and representatives from all of the different steering committees get together to meet face to face. He discussed the need for a Ph.D. program in clinical and translational research and better integration of informatics into clinical research. People could train across centers, have pilot grants, and develop other ways to facilitate collaboration across CTSAs. All CTSAs should network for important clinical trials, particularly NIH clinical trials, and develop best practices.

Guzick (Rochester) wants better ways to: disseminate clinical and translational research into communities; translate infrastructure to economic development and leveraging of infrastructure with industry partners and to use resources in terms of mentoring, laboratory experiences, and curricula to best effect.

Ginsberg (Columbia) wants the CTSA program to give researchers experience to move research forward. He sees opportunities for the CTSA Consortium to train individuals in translational research and recognizes the value of more integration within and across institutions.

Arnett (UT Houston) explained that in the post-genomic era we should share genetic data from association studies of complex diseases, and post the gene frequencies for local controls on a website for comparisons among CTSAs and others, as well as allow others to use these normal controls from different ethnic groups instead of repeating the genotyping.

Gallin (NIH Clinical Center) wants to make the Clinical Center an active partner with the CTSA Consortium, making it more accessible to clinical researchers who require unique resources, such as metabolic chambers, cyclotrons and high resolution imaging. Goals include improving the experience for research participants and improving the process of informed consent.

Kurilla (NIAID) summarized the discussion and noted that development of the CTSAs is hoped to be a transformative process, which already seems to have started during the development of the grant applications.

NIH Interactions With the CTSA Consortium

The PI Steering Committee and other steering committees will provide opportunities for scientific interaction between CTSA representatives and NIH Science Officers, who are members of the NIH CTSA Project Team and will serve on the Steering Committees but do not directly oversee any of the CTSAs. Additional steering committees are envisioned for all 'key function" areas including participant/clinical interactions, evaluation, pediatrics, clinical research ethics, translational, communications, resource access, education and career development, industrial partners, biomedical informatics, and others as needed.

Programmatic interactions will come from NCRR Program Officers. These officers participate in the CTSA Project Team but will not be voting members on steering committees since they directly manage the awards. NCRR program officers will be responsible for reviewing annual progress reports and external advisory committee reports, and possibly conducting site visits. In addition, information also needs to flow to the NCRR Office of Grants Management (OGM) as well as budget officials, and the program officials would report to the NCRR Director.

Dr. Coller commented that the items discussed by the Principal Investigators' meeting could provide focus for the steering committees. He stated that there is a need to ensure that representation on committees meets the desired goals and that there may be the need for further discussion about how the committees will be formulated and crafted.

PIs were informed that the costs for attending CTSA meetings would have to be born by awardees, and that every attempt would be made to use videoconferencing effectively.

The prioritization and implementation of Steering Committees was discussed, with proposals for a quarter-by-quarter plan. The next Steering Committees will be (1) Evaluation and (2) Informatics and (3) Research Education. Dr. Jill Joseph of UC, Davis, suggested that it might be important to have a committee that would monitor barriers that have been encountered and how they may be overcome.

Evaluation Strategies

Ms. Mulligan (NCRR) explained that the great expectations for the CTSA program require a rigorous evaluation strategy. Congress has requested reports on support of clinical investigators in March 2007, clinical and translational research in April 2007, and status of GCRCs/CTSAs in July 2007. A trans-NIH CTSA Evaluation Subcommittee has been established and will identify important common baseline metrics and their collection. The National CTSA Evaluation Steering Committee will meet by early next year, finalize a plan for process evaluation in May 2007, and submit a report on CTSA evaluation status to the Congressional Appropriations Committee by July 1, 2007.

Ensuring Access to CTSA Resources

Dr. Pihlstrom (NIDCD) discussed access to CTSA resources, asking how CTSAs can assure that these resources will be shared fairly and how to provide access to various disciplines within institutions such as pediatrics, public health, and communities.

Supplements to National Clinical Research Associate (NCRA) Program

Dr. Alexander (NICHD) explained that the NCRA model developed by RAND, which envisioned 40 research organizations that consisted of 40,000 to 60,000 practitioners, was more costly than NIH could currently afford. Instead, an RFA for CTSAs to plan for community-based practice networks based on the NCRA model could be issued. There would be requirements for enrolling, training, and credentialing. Applications would be reviewed and awarded based on these criteria. CTSA PIs expressed interest in the idea, which Dr. Alexander will pursue.

Principal Investigator Issues

PIs expressed concern about running CTSAs on a budget that did not allow for annual increases. Dr. Alving said that NIH has been impressed that investigators have received funding from other sources. She mentioned the amount of leverage that can be obtained by having a CTSA or NIH award and said that institutions would need to look at the ability to leverage what they have from NIH.

PIs acknowledged that investigators live in a world of constrained resources. While there will be no automatic carryovers, NCRR will consider justified requests.

Scheduling Issues

Good Web site and Internet communication are essential, but there is no substitute for telephone calls and face-to-face meetings. Quarterly face-to-face meetings would be desirable but costly. Dr. Califf suggested having face-to-face meetings by incorporating them with professional meetings.

Public and CTSA-Specific Communication

Dr. Obrams (NCRR) showed a prototype Web site that would link to each of the centers, with a click on a site to see what projects are going on in the location. An e-newsletter may also be available for viewing or downloading. This site would be separate from the existing NIH CTSA site, which would provide government information only. A portion of the site would be a password-protected member login and could have multiple portals including such features as data sharing, updates, and reports. An ".org" site is preferred.

For Web site development, determination of all possible users and how they would connect to site was recommended. The site was also suggested as a place to access a standard application form, requirements, etc. Now may also be the time to have a

committee addressing these issues. One of the key questions raised was how to effectively communicate with the public, pharmaceutical industry, etc., and it was suggested that a contractor may be needed to organize and maintain the site.

Next Meeting

The time of the next meeting was discussed, and there seemed to be agreement to meet in about 6 months—sometime after May 1st. Participants stated that the sooner a date was chosen the better.

The meeting was adjourned at 2:55 P.M.

Summary of Key Discussion Points

- Participant goals include developing a cadre of clinical and translational researchers through improved training, strengthening national links between institutions, developing standards for bioinformatics and academic-industry partnerships, improving recruitment to clinical trials, enhancing relationships with the community, and investigating definitions of phenotypes.
- Both NIH staff and CTSA PIs emphasized the importance of sharing and collaborative nature of the CTSA program.
- Role of External Advisory Boards may change as the program evolves, but it may be important to have these in place by April 2007.
- Regarding Steering Committees, Evaluation Steering Committee appears to be the next steering committee to be developed, with clinical informatics, education and training, and ethics mentioned as next priorities. The exact structure within the steering committees remains to be determined but may include an NIH facilitator. Additional committees may include participant/clinical interactions, pediatrics, translational, communications, resource access and industrial partners.
- Having efficient systems in place before continued expansion of the program would aid in the success of the initiative.
- Promoting access to resources may require evaluation of researchers who failed to get what they had hoped from their CTSA.
- Participants indicated interest in applying for the NCRA award as a supplement to the CTSA program.
- Several concerns were raised about dealing with the absence of cost-of-living increases and carryover issues.
- Participants were supportive of the CTSA Consortium Web site and suggested that institutions collaborate from the beginning to ensure efficiency.
- Face-to-face meetings are desirable, especially in early stages, but budget constraints may require pursuit of alternative options, such as teleconferencing.

Action Items

- NCRR will collect nominations for individuals to serve on the Evaluation and "key function" steering committees.
- Meet again in approximately 6 months and determine date for meeting soon.
- Institutions should discuss with NCRR personnel strategies for transition of prior K12 and T32 awards to CTSA.